REMARKS

This submission is in response to the Restriction Requirement dated November 26, 2001. Claims 2-4 and 15-22 have been canceled, without prejudice or disclaimer. New claims 25-34 have been added. Claims 1, 6, 8, 13, 14, 23 and 24 have been amended. Thus, claims 1, 5-14, and 23-34 are pending.

Claims 1, 6, and 14 have been amended to call for a recombinant polyclonal antibody. Claims 8, and 13, 14 have been amended to conform to U.S. claim terminology. In addition, claims 23 and 24 have been amended to independent form, and to call for a "polyclonal antibody preparation." This amendment is supported, *e.g.*, at page 10, line 29 to page 12, line 12; and page 13, lines 16-28, of the specification.

New claims 25-34 are all supported by the specification as filed. In particular, the Examiner's attention is directed to the following sections of the specification where the subject matter of claims 25-34 is described: page 10, lines 4-17; page 18, line 22 to page 19, line 14; page 20, line 2 to page 24, lines 11; and page 25, line 17 to page 21, line 7.

No new matter has been added by way of this amendment.

Restriction Requirement

In the Restriction Requirement, the Examiner has required election of one of the following groups of claims:

Group I. Claims 1-2 and 5-14, directed to a pharmaceutical composition comprising a recombinant polyclonal antibody.

Group II. Claims 1, 3, 5-9, and 13-14, directed to a pharmaceutical composition comprising a mixture of individual monoclonal antibodies.

Group III. Claims 1, 4-9, and 13-14, directed to a pharmaceutical composition comprising an isolated or purified polyclonal antibody.

Group IV. Claims 15-18 and 21-22, directed to the use of a recombinant polyclonal antibody for the manufacture of a pharmaceutical composition.

Group V. Claims 15-17 and 19, directed to the use of a mixture of individual monoclonal antibodies for manufacturing a pharmaceutical composition.

Group VI. Claims 15-17 and 20, directed to the use of an isolated or purified polyclonal antibody for the manufacture of a pharmaceutical composition.

Group VII. Claims 23-24, directed to a method of preventing or treating allergy comprising administering a recombinant polyclonal antibody.

Group VIII. Claims 23-24, directed to a method of preventing or treating allergy comprising administering an isolated or purified polyclonal antibody.

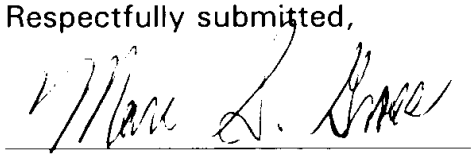
In response, Applicants hereby elect Group I, corresponding to claims 1-2 and 5-14, with traverse. It is respectfully submitted that the various groups are but parts of a unitary invention, involving the preparation or use of pharmaceutical compositions incorporating a polyclonal antibody preparation which reacts with or binds to an allergen. It is urged that all of the pending claims can be examined in this application without imposing any undue burden on the Examiner, or necessitating the filing of one or more divisional applications with consequent additional burden on both applicants and the Office.

However, solely for the purpose of advancing the prosecution of this application, Applicant has amended claims 1, 6, and 14 to call for a recombinant polyclonal antibody. In addition, claims 15-22 have been canceled, without prejudice or disclaimer. Thus, only claim groups I, VII, and VIII remain for restriction purposes, further lessening the examination burden on the Examiner if all pending claims were to be examined in this application. Accordingly, reconsideration and withdrawal of the Restriction Requirement, in particular as applied to Groups I, VII, and VIII, is urged.

An early Office Action on the merits of this application is earnestly solicited.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,



Marc S. Gross
Reg. No. 19,614
Attorney for Applicants

DARBY & DARBY, P.C.
805 Third Avenue
New York, N.Y. 10022
Phone (212) 527-7700

M:\4305\1J396US1\BAR2812.FRM

EXPRESS MAIL CERTIFICATE

Date 1/22/02 Label No. EL 767719835 US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

D. Davis D. Davis

Name (Print) Signature

PLEASE CHARGE ANY DEFICIENCY UP TO $300.00 OR CREDIT ANY EXCESS IN THE FEES DUE WITH THIS DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Customer No.: 07278

PATENT TRADEMARK OFFICE

Docket No: 4305/1J396US1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: John S. HAURUM et al.

Serial No.: 09/866,573 Art Unit: 1644

Confirmation No.: 4477

Filed: May 25, 2001 Examiner: M.E. Jamroz

For: **A POLYCLONAL ANTIBODY COMPOSITION FOR TREATING ALLERGY**

MARK-UP FOR RESPONSE TO RESTRICTION REQUIREMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

January 22, 2002

Sir:

IN THE CLAIMS:

Please amend the claims according to 37 C.F.R. 1.121:

1. (Amended) A pharmaceutical composition comprising as an active ingredient a recombinant polyclonal antibody [or a mixture of individual monoclonal antibodies or an isolated or purified polyclonal antibody] capable of reacting with or

binding to an allergen, together with one or more pharmaceutically acceptable excipients.

6. (Twice amended) A pharmaceutical composition according to claim 1, comprising at least one pharmaceutically acceptable excipient capable of effecting topical application of said recombinant polyclonal antibody [or said mixture of individual monoclonal antibodies or said isolated or purified polyclonal antibody].

8. (Amended) A pharmaceutical composition according to claim 7, wherein the respiratory tract is selected from [comprises the] nasal, oral, pharyngeal, bronchial, or alveolar mucosa.

13. (Twice amended) A pharmaceutical composition according to claim 1, wherein the allergen is an allergen of house dust mites, *[e.g. Dermatophagoides farinae* or *D. pteronyssimus*;] dander from cat, [dot] dander from dog, [or] dander from horse[;], tree pollen, [*e.g.* pollen from birch (Betula alba), alder, hazel, oak, willow, plane, beech, elm, maple, ash, mugwort (Artemisia) and hornbeam;] grass pollen, [*e.g.* pollen from timothy grass (*Pheleum pratense*), blue grass (*Poa pratense*), rye grass (*Lolium perenne*), Orchard grass (*Dactylis glomerata*), ragweed (*Ambrosia artemisiifolia*), sweet vernal grass (*anthoxanthum odoratum*), and rye (*Secale cereale*);] or fungi [(*e.g. Alternaria, Aspergillus, Cladosporium* and *Penicillium*)].

14. (Twice amended) A pharmaceutical composition according to claim 1, comprising the recombinant polyclonal antibody [or the mixture of monoclonal antibodies or the isolated or purified polyclonal antibody] in an amount in the range of 1μg to 1g [, preferably 1-1000 μg, more preferably 2-500 μg, even more preferably 5-50 μg, most preferably 10-20 μg] per unit dosage form.

23. (Twice amended) A method of preventing or treating [allergy] an allergic reaction in a patient in need thereof, which method comprises administering to [a] the patient [in need thereof] a composition [according to claim 1] comprising [a sufficient amount of] a polyclonal antibody preparation capable of reacting with or binding to an allergen to which the patient has shown or is predisposed to develop an allergic [reactions] reaction, and a pharmaceutically acceptable excipient,

wherein the composition comprises a sufficient amount of polyclonal antibody preparation to prevent or treat the allergic reaction.

24. (Twice amended) A method of inducing tolerance to an allergen [which comprises administering to] in a patient who would [untreated] be likely to show an allergic reaction to the allergen if untreated, which method comprises administering to the patient a composition [according to claim 1] comprising [a sufficient amount of] a polyclonal antibody preparation capable of reacting with or binding to the allergen and induce tolerance to the allergen in the patient, and a pharmaceutically acceptable excipient,

wherein the composition comprises a sufficient amount of polyclonal antibody preparation to induce tolerance to the allergen in the patient.